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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,178	08/20/2003	Robert L. Ibsen	00216-695001	9505

27777 7590 01/18/2007
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EXAMINER

JAGOE, DONNA A

ART UNIT	PAPER NUMBER
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1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary**Application No.**

09/914,178

Applicant(s)

IBSEN ET AL.

Examiner

Donna Jagoe

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 27, 2006 has been entered.

Claims 21-31 are pending in this application.

Applicants' arguments, filed November 27, 2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker U.S. 4,602,099 and Dyer et al U.S. Patent No. 5,994,383 (reference AI from IDS dated 1/25/02).

Parker teaches a mouthwash formulation (column 5, lines 20-23) comprising inter alia water (column 5, line 48), carbomers (column 5, line 59), benzocaine (column 6, line 62) and triethanolamine (column 5, line 65). It does not teach the amounts of these agents. One skilled in the art would have been motivated to prepare additional useful compositions of the ranges taught by the prior art. While the reference is silent

regarding some % ratios, the difference in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. When the general conditions are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 45, 105 USPQ 233, 235 (CCPA 1955). In the absence of any criticality and/or unexpected results of the additional ranges claimed, instant invention is considered obvious. Further, the claim language *comprising* leaves the claim open for the inclusion of unspecified ingredients, even in major amounts, and does not exclude the amounts, if any in the reference. It does not teach the triethanolamine to be a neutralizing agent. However, Dyer et al. teach that triethanolamine is a commonly used alkalination agent (column 11, lines 60-61). "Products of identical chemical composition (i.e. triethanolamine) can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical composition, the properties applicant discloses and/or claims (i.e. neutralizing or buffering) are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymer latexes for lack of novelty."). It would have been made obvious to one of ordinary skill in art at the time it was made to formulate a composition comprising benzocaine, carbomer and water in an alcohol

free solvent system motivated by the teaching of Parker that teaches a mouthwash formulation that includes these agents, and Dyer et al. that teaches that triethanolamine is a commonly employed alkalination agent.

Claims 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singleton et al. U.S. Patent No. 5,547,657.

Singleton et al. teach a low irritation anesthetic mouth rinse (see abstract) comprising a non-alcoholic formulation (column 1, lines 60-62) of a topical anesthetic such as benzocaine (column 1, line 44, column 2, line 27) and a carbomer such as Poloxamer 407 (see example XIII and XIV, column 9). The amounts of benzocaine, carbomer and water differ from the instant invention. One skilled in the art would have been motivated to prepare additional useful compositions of the ranges taught by the prior art. While the reference is silent regarding some % ratios, the difference in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. When the general conditions are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 45, 105 USPQ 233, 235 (CCPA 1955). In the absence of any criticality and/or unexpected results of the additional ranges claimed, instant invention is considered obvious. Further, the claim language *comprising* leaves the claim open for the inclusion of unspecified ingredients, even in major amounts, and does not exclude the amounts, if any in the reference.

Response to Arguments

Applicant asserts that Parker discloses anti-rhinovirus agent and various means for delivering such agents. Applicant admits that Parker does disclose a mouthwash and asserts that it is for the purpose of delivering the claimed agents. In response to applicant's argument, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Applicant asserts that Parker discloses benzocaine merely as one in an extremely long list of potential agents that may be combined with the anti-rhinovirus agents. And carbomers are mentioned only as a possible suspending agent amongst others listed. During patent examination claims must be interpreted as broadly as they reasonably allow, in order to achieve complete exploration of applicant's invention and its relationship to prior art, so that ambiguities can be recognized, scope and breadth of language explored, and clarification imposed. Accordingly, the claim language *comprising* leaves the claim open for the inclusion of unspecified ingredients, even in major amounts. Applicant asserts that the only solutions exemplified in Parker are Examples 11 and 21 and Example 11 utilizes water without benzocaine or carbomer. Applicant further charges that Example 11 contains substantial amounts of alcohol and polyethylene glycol. In response, a reference is good not only for what it teaches by the direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re Opprecht* 12 USPQ2d 1235, 1236 (Fed. Cir. 1989); *In re Bode* 193

USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

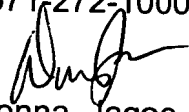
Regarding the Singleton reference, although applicant asserts that the instant invention is free of the monohydric alcohols that are incorporated in Singleton, upon inspection of the applicant's instant specification, page 10, example 2 discloses an example of the alcohol-free oral rinse made using "non-alcoholic organic solvents such as propylene glycol and polyethylene glycol instead of carbomer". During patent examination claims must be interpreted as broadly as they reasonably allow, in order to achieve complete exploration of applicant's invention and its relationship to prior art, so that ambiguities can be recognized, scope and breadth of language explored, and clarification imposed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Donna Jagoe
Patent Examiner
Art Unit 1614

January 8, 2007


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER